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APPLICATION NO. 09/407,806	FILING DATE 09/28/99	FIRST NAMED INVENTOR MURPHY	ATTORNEY DOCKET NO. DIVER1120-1
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HM22/0831

EXAMINER TUNG, P

ART UNIT 1652	PAPER NUMBER
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DATE MAILED:

08/31/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/407,806

Applicant(s)

Murphy et al.

Examiner

Peter Tung

Group Art Unit

1652



☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-23 is/are pending in the application.

Of the above, claim(s) 10-12 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-9 and 13-23 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 3

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

1. Claims 1-23 are pending.

Election/Restriction

2. Applicant's election of Group I, claims 1-9, in Paper No. 6, dated 7/20/00 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
3. Claims 10-12 are withdrawn from further consideration as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 5, 15 and 16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The DNA encoding AEDII2RA- α -gal-18GC must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If a deposit is

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made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. *See 37 CFR 1.808.* Further, the record must be clear that the deposit will be maintained in a public depository for a period of 30 years after the date of deposit or 5 years after the last request for a sample **or for the enforceable life of the patent whichever is longer.** *See 37 CFR 1.806.* If the deposit has not been made under the Budapest treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature must be made, stating that the deposit has been made at an acceptable depository and that the criteria set forth in 37 CFR 1.801-1.809, have been met. Applicant's attention is directed to *In re Lundak*, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985), and 37 CFR 1.801-1.809 for further information concerning deposit practice.

6. Claims 1, 13-16, 14 and 19, are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polynucleotide which encodes SEQ ID NO: 4 or is 90% identical to a polynucleotide which encodes SEQ ID NO: 4 and which has alpha galactosidase activity, does not reasonably provide enablement for a polynucleotide which is at least 70% identical to a polynucleotide encoding an enzyme comprising SEQ ID NO: 4 or which

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has 90% identity under stringent conditions to a polynucleotide encoding SEQ ID NO: 4 or AEDII2RA- α -gal-18GC. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the breadth of the claims. The breadth of the claims encompass any enzyme which is at least 70% identical to said polynucleotides. Insufficient guidance and insufficient examples have been provided on those polynucleotides which are 70% identical to said polynucleotides and which do not encode an alpha galactosidase. Undue experimentation would be required to enable the full scope of the claims based upon the limiting scope of the disclosure.

7. Claim 17 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Adequate description for the species encompassed by the claim would have relevant identifying characteristics which include 1) structure, 2) physical and/or chemical characteristics, 3) functional characteristics when coupled with a known or disclosed correlation between function and structure, 4) a combination of these. The instant claims are drawn to

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genomic DNA encoding an alpha galactosidase. However, the structure of genomic DNA entails more than just the coding sequence of a protein but also includes the regulatory, promoter and terminator sequences that precede and follow the coding sequence. Adequate description of the structure of genomic DNA would include all of these sequences. The instant application discloses coding sequences of DNA but not regulatory, promoter and terminator sequences. Therefore the complete structure of the gene is inadequately described.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claim 5 is indefinite as the deposit number is omitted.

11. Claim 19 is indefinite as it is unclear what the metes and bounds are of a "non-coding sequence". It is not clear if this sequence is meant to be a complementary sequence.

Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 1-9 and 13-23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3-14 of U.S. Patent No. 5,958,751.

Although the conflicting claims are not identical, they are not patentably distinct from each other because SEQ ID NO: 3 and a polynucleotide encoding the amino acid sequence of SEQ ID NO: 4 would be the same polynucleotide as one having at least 70% identity to a polynucleotide encoding the enzyme of SEQ ID NO: 4 or AEDII2RA- α -gal-18GC. Similarly, expression vectors comprising the polynucleotide, transformed host cells, and methods of expressing the protein are not patentably distinct.

14.

15. *Claim Rejections - 35 USC § 102*

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

17. Claims 1-3, 5-9 and 17-23 are rejected under 35 U.S.C. 102(e) as being anticipated by Sogabe et al. Sogabe et al. teach (column 3, line 5-column 7, line 67; SEQ ID NO: 2, cols. 15-

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20)an isolated polynucleotide comprising as least 15 nucleotides of SEQ ID NO: 4 (nt 1412-1426 of Sogabe et al. SEQ ID NO: 2, polynucleotide encoding amino acid residues 120-124 of instant SEQ ID NO: 4), a vector comprising said polynucleotide, transformed host cells and a method of making protein, which is that of the instant claims.

18. No claims are allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter Tung, Ph.D. whose telephone number is (703) 308-9436. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, Ph.D., can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


CHARLES L. PATTERSON, JR.
PRIMARY EXAMINER
GROUP 1800